OCT 2 9 2001

K012462

Theken Large Cement Restrictor

510 (k) Summary

Company: Theken Surgical
1100 Nola Ave.
Barberton, OH 44203

Trade Name: Theken Large Cement Restrictor

Classification: JDK 21CFR878.3300. Surgical Mesh. Class II.

Description:

The Theken Large Cement Restrictor is titanium, hollow, rectangular frame with fenestrations and radii on all sides and toothed spikes on opposite sides. The device is intended to be used in conjunction with standard PMMA cement.

Performance Data:

Non-clinical:

Static evaluation was performed and the strength of the device was characterized.

Intended Use:

The Theken Large Cement Restrictor is designed to occlude the medullary canal before the introduction of acrylic cement during surgeries such as total hip arthroplasty, as well as prevent cement from flowing down the diaphysis thereby facilitating cement pressurization. The Theken Large Cement Restrictor is NOT intended for any spinal indications.

Substantial Equivalence:

Signus Medizintechnik GmbH Rabea™ Cement Restrictor Device (K990345)
Medtronic Sofamor Danek Titanium Cement Restrictor Device (K003718)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2001

Mr. Randy Theken
Director
Theken Surgical, LLC
1100 Nola Avenue
Barberton, Ohio 44203

Re: K012462
Trade/Device Name: Theken Large Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: July 31, 2001
Received: August 1, 2001

Dear Mr. Theken:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

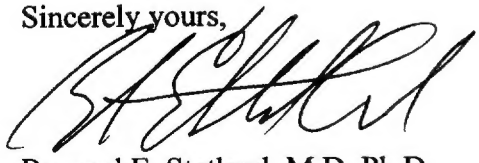
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address:
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bernard E. Statland, M.D.,Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number: K012462

Device Name: Theken Large Cement Restrictor

1. Indications for Use:

The Theken Large Cement Restrictor is designed to occlude the medullary canal before the introduction of acrylic cement during surgeries such as total hip arthroplasty, as well as prevent cement from flowing down the diaphysis thereby facilitating cement pressurization. The Theken Large Cement Restrictor is NOT intended for any spinal indications.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1/2/96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012462